Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2940102

December 12, 2000

Richard Aschieris, Port Director
Port of Stockton Ore Dock 2-13
2201 West Washington Street
Stockton, CA 95203

WARNING LETTER

Dear Mr. Aschieris:

This Warning Letter amends the Warning Letter issued on December 6, 2000. The port was misidentified on page 2 of the original letter. We apologize for any inconvenience.

The U.S. Food and Drug Administration (FDA) conducted an inspection of the watering point services located at the Port of Stockton Ore Dock 2-13, 2201 Washington Street, Stockton, CA. Your operations at this site are in serious violation of Section 361 of the Public Health Service Act and Title 21, Code of Federal Regulations, Part 1250, Interstate Conveyance Sanitation.

Lack of adequate water system protection was demonstrated by the following observations:

Berth Area:

1. The hose used to provide water to the vessel at Berth A is connected directly to the potable water system without a backflow prevention device.
2. Two of the 20 potable water outlets at Berth A-K were left uncapped while not in use.
3. All 20 potable water outlets at Berth A-K are not identified as drinking water; fire system hydrants are also located on the same pier.

Dock Area:

1. The potable water outlet connected to a PVC pipe is attached to a garden hose used for cleaning boats and has no backflow prevention device.
2. The pit drain at Dock 10 is clogged with debris, and there is standing water inside of the pit.
3. Ten potable water outlets located at Dock 3-12 were either left uncapped or were missing their caps.

4. Bird excreta and nesting materials were observed surrounding an uncapped outlet of the potable water system at Dock 9.

The three reduced pressure zone backflow devices are not tested annually.

The ends of the detachable plastic outlet to the reduced pressure zone backflow device were left uncovered while not in use and were missing their caps.

Four potable water outlets used to provide potable water to vessels and tug boats at Berth A-K have no backflow prevention protection.

The findings were discussed with Mr. Michael Tyler, Operations Manager, at the conclusion of the inspection. Copies of the Form FDA 483 and Form FDA 2521, Inspection Summary--Vessel Watering Point Sanitation, were issued to Mr. Tyler and are being provided to you for your information.

Based on these findings, your facility has been classified "Provisional." A Provisional classification means that if the deficiencies are not corrected within thirty (30) working days from the receipt of this notification, your facility will be placed on "Not Approved" status. A "Not Approved" status means that potable water will be prohibited from use by interstate conveyances at the Port of Stockton.

Failure to take prompt corrective action may result in appropriate regulatory action, such as injunction without further notice. You should notify this office within fifteen (15) working days of the receipt of this letter of the specific steps you have taken to correct the violations. If corrective action cannot be completed within thirty (30) working days, cite the reason for the delay and the time by which the corrections will be completed. Your response should be sent to:

Randall P. Zielinski, CSO/ITS
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502-7070

You may wish to FAX your response to Mr. Zielinski at (510) 337-6703.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District

Enclosures: Form FDA 483
Form FDA 2521

cc: Mr. Michael Tyler, Operations Manager
Port of Stockton Ore Dock 2-13
2201 Washington Street
Stockton, CA 94201